

### REMARKS

The applicants have studied the Office Action dated August 27, 2003, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1-11 and 21-23 are pending. Claims 1 and 8 should be amended, and new claims 21-23 should be added. Consideration and allowance of all of the claims in view of the above amendments is respectfully requested.

Applicants confirm the election to prosecute the invention of group (I) covered by claims 1-11. Claims 12-20 have been withdrawn as being directed to a non-elected invention. The applicants expressly reserve the right to file a divisional application directed to this subject matter at a later date.

The drawings were objected to under 37 CFR 1.83(a) because the Examiner believes that the limitation found in claim 5 was not shown in the drawings. Moreover, claim 5 was further objected to under 37 CFR 1.75(d) (1) and MPEP § 608.01(o) for failing to provide proper antecedent basis for the claimed subject matter (i.e. there is no disclosure of the subject matter of the one-way valve). These objections are respectfully traversed.

Figure 2 has been amended to include element 5 (i.e. the one-way valve). Moreover, antecedent is found in the specification for the one-way valve in paragraph [0022], which states: "around the sensor tip 23, the flush sleeve 30 contains a small orifice 32, which comprises a one-way valve 5, to allow fluid to spray off the sensor tip 23" (emphasis added). Accordingly, it is respectfully submitted that the objection to the drawings and the objection under 37 CFR 1.75(d) (1) and MPEP § 608.01(o) are overcome and should be withdrawn.

Claim 8 was rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. This rejection is respectfully traversed.

Claim 8 was rejected because the limitation “affixed internally to the patient” is non-statutory. As suggested by the Examiner, claim 8 has been amended to recite “affixable internally to the patient” (emphasis added). Accordingly, it is respectfully submitted that this rejection is now moot and the rejection should be withdrawn with respect to claim 8.

Claims 1-4, 6, and 8-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,432,366 to Margules. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an implantable sensor apparatus having a flush sleeve over the length of the sensor to allow fluid delivered through the flush sleeve spray the sensor tip. Specifically, the flush sleeve concentrically surrounds the implantable sensor (emphasis added). Amended independent claim 1 (and thus dependent claims 2-4, 6, and 8-10) now recites “a flush sleeve directed towards the sensor tip; and a fluid conduit in fluid communication with the flush sleeve, wherein a fluid received in the fluid conduit in fluid communication with the flush sleeve is used to spray the sensor tip, wherein the flush sleeve concentrically surrounds the implantable sensor around a generally common axis” (emphasis added). Support for these limitations exist throughout the specification. For example, the specification reads: “the implantable sensor 20 includes a flush sleeve 30 in a tight fit connection surrounding the sensor 20, which allows fluid communication along the length of the sensor 20” (emphasis added)(See page 7, lines 9-11). No new matter has been added. The Margules reference does not disclose, teach, or suggest a flush sleeve that concentrically surrounds the sensor, as recited in the claims.

The Margules reference is directed to a catheter that contains a single passageway in parallel with the sensor device. Specifically, the Margules reference discloses a single passageway 16 “for either the infusion of a calibrating liquid or for the infusion of a liquid which serves to flush the outer surface of the membrane 34” (see col. 4, lines 26-29). Given that the passageway 16 in the Margules reference is directed to only spot on the sensor, the function of the passageway 16 is limited. For example, the single passageway 16 in the Margules reference

cannot spray the entire sensor tip, but rather only at the specific location that the passageway ends. In addition, unlike a flush sleeve surrounding the entire sensor, if the side of the sensor that the passageway 16 is somehow kinked, the passageway can no longer serve its purpose. Nowhere in the Margules reference describes a flush sleeve that concentrically surrounds the implantable sensor around a generally common axis.

Therefore, it is respectfully submitted that the rejection of claims 1-4, 6, and 8-10 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 1, 2, and 4-10 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,224,585 to Pfeiffer. This rejection is respectfully traversed.

As mentioned above, embodiments of the present invention are directed to an implantable sensor apparatus having a flush sleeve that concentrically surrounds the implantable sensor (emphasis added). Amended independent claim 1 (and thus dependent claims 2 and 4-10) now recites “a flush sleeve directed towards the sensor tip; and a fluid conduit in fluid communication with the flush sleeve, wherein a fluid received in the fluid conduit in fluid communication with the flush sleeve is used to spray the sensor tip, wherein the flush sleeve concentrically surrounds the implantable sensor around a generally common axis” (emphasis added). The Pfeiffer reference does not disclose, teach, or suggest a flush sleeve that concentrically surrounds the sensor, as recited in the claims.

The Pfeiffer reference discloses a double lumen catheter having one lumen for sensor and another lumen for either delivering or suctioning out fluid around the sensor tip, where the two lumens are in a side-by-side configuration. Specifically, the Pfeiffer reference describes a shaft wall 1a that divides the catheter into two lumens, one for the sensor and the other as a pressure lumen, in a side-by-side configuration (see col. 5, lines 35-50 and Figure 2). The pressure lumen 2 is described as being able to deliver heparinized flushing solution to the tip (see col. 6, lines 13-17). As mentioned previously with regards to a side-by-side configuration, the lumen 2 in the

Pfeiffer reference is directed to only spot on the sensor tip and thus the function of the pressure lumen is limited. Nowhere in the Pfeiffer reference describes a flush sleeve that concentrically surrounds the implantable sensor around a generally common axis.

Therefore, it is respectfully submitted that the rejection of claims 1, 2, and 4-10 under 35 U.S.C. § 102(e) should be withdrawn.

Claims 1, 4, 6, 9 and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,478,222 to Koning et al. This rejection is respectfully traversed.

As mentioned above, amended independent claim 1 (and thus dependent claims 4, 6, 9 and 10) now recites “a flush sleeve directed towards the sensor tip; and a fluid conduit in fluid communication with the flush sleeve, wherein a fluid received in the fluid conduit in fluid communication with the flush sleeve is used to spray the sensor tip, wherein the flush sleeve concentrically surrounds the implantable sensor around a generally common axis” (emphasis added). The Koning et al. reference does not disclose, teach, or suggest a flush sleeve that concentrically surrounds the sensor, as recited in the claims.

The Koning et al. reference discloses a double lumen catheter having one lumen for the sensor and another lumen for sampling the blood and also delivering a calibration liquid, where the two lumens are in a side-by-side configuration. Specifically, the Koning et al. reference states “the catheter 14 has two lumina 15 and 16 separated by a common partition 17” (see col. 3, lines 10-11 and Figure 3), wherein “by supplying calibration liquid through channel 15, the blood present therein is expelled and the sensor can be calibrated (see col. 3, lines 19-21). The Examiner has interpreted this teaching as also being able to flush the sensor using the calibration liquid. Regardless, as mentioned previously with regards to a side-by-side configuration, the channel 15 in the Koning et al. reference is directed to only spot on the sensor tip and thus the function of the channel 15 is limited. Nowhere in the Koning et al. reference describes a flush sleeve that concentrically surrounds the implantable sensor around a generally common axis.

Therefore, it is respectfully submitted that the rejection of claims 1, 4, 6, 9 and 10 under 35 U.S.C. § 102(e) should be withdrawn.

Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Margules (U.S. Patent No. 4,432,366) in view of Gough et al. (U.S. Patent No. 4,703,756). This rejection is respectfully traversed.

Claim 11 depends on independent claim 1, which are patentably distinguished over the Margules reference as discussed above. Accordingly, claim 11 is also distinguished over the Margules reference.

The Gough et al. reference does not make up for the deficiencies of the Margules reference. The Gough et al. patent is directed to “an implantable electrochemical glucose monitoring system” (See Summary, col. 3, lines 6-7). The Examiner cited the Gough et al. reference for the proposition that it “wirelessly transmitting signals from a device inside the body to monitor outside the body is an alternate way of communicating patient data to a monitor” (see page 6 of the Office Action). The combination of the Gough et al. reference with the Margules reference does not describe, teach, suggest or otherwise render obvious the claimed subject matter because the cited sections of the Gough et al. reference do not disclose, teach, or suggest a flush sleeve that concentrically surrounds the implantable sensor around a generally common axis.

Therefore, it is respectfully submitted that the rejection of claim 11 under 35 U.S.C. § 103(a) should be withdrawn.

New claims 21-23 have been added by this amendment and are provided to further define the present invention. New claims 21-23 describe an implantable multi-lumen sensor apparatus for taking readings from a patient in vivo wherein the implantable sensor is an inner lumen and an outer lumen comprising a flush sleeve surrounds the inner lumen in a generally coaxial manner. The limitations of claims 21-23 are supported in the specification and cover the embodiment as described in FIG. 2. No new matter was added. None of the cited references, either alone or in combination, describe, teach or suggest an outer lumen comprising a flush sleeve surrounding the inner lumen in a generally coaxial manner as recited in new claims 21-23. Therefore, it is respectfully submitted that claims 21-23 are also patentable over the prior art.

Therefore, in light of the above amendment and remarks, it is respectfully submitted that claims 1-11 and 21-23 are in condition for allowance.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Northridge, California, telephone number (818) 576-4110, to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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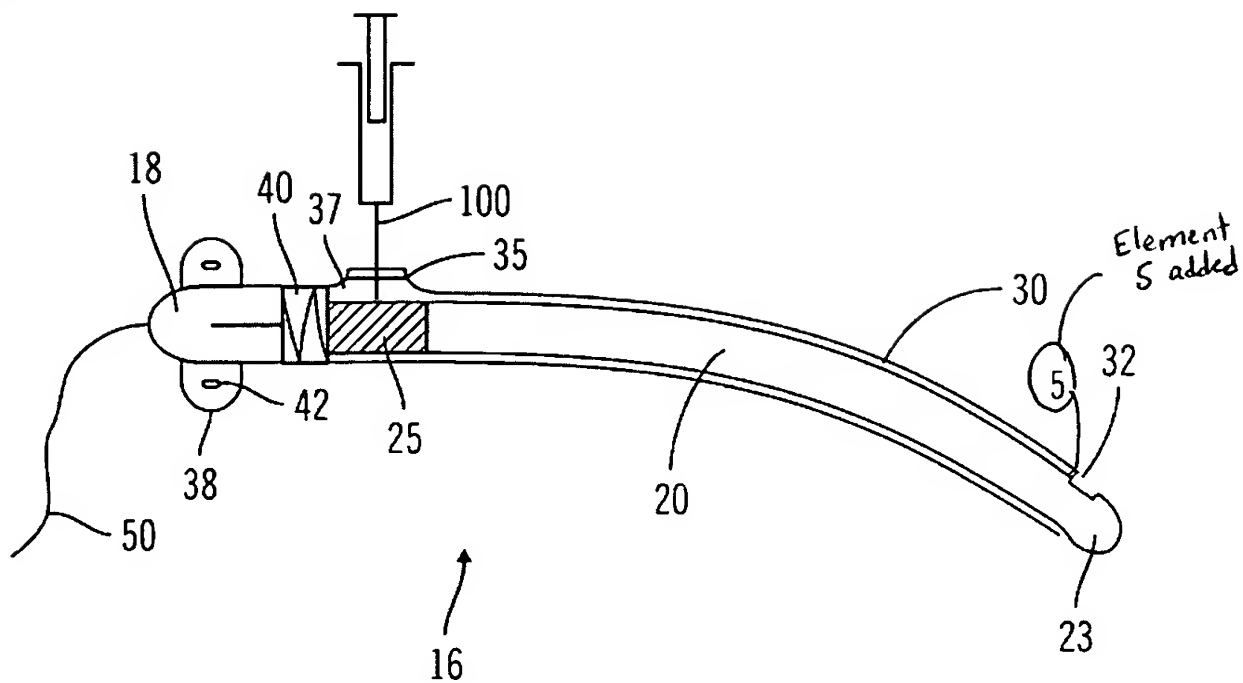


FIG. 2